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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/036,959 | 01/02/2002 | David L. Hallahan | CL1792 US NA | 4565 |

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--|--|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | <p>Application No. 10/036,959</p> | <p>Applicant(s) HALLAHAN ET AL.</p> | |
| | <p>Examiner Kathleen M. Kerr</p> | <p>Art Unit 1652</p> | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

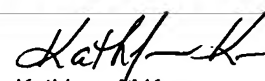
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached action.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 2/18/05
13. ☒ Other: PTO-892.


Kathleen M Kerr
Primary Examiner
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DETAILED ACTION

Application Status

1. A final rejection was mailed on October 19, 2004 rejecting claims 29-31 and 34-40 and objecting to Claims 32-33. The instant Office action is in response to Applicant's request for reconsideration after final rejection of Claims 29-31 and 34-40, with Claims 32-33 being objected to, filed February 18, 2005.

Information Disclosure Statement

2. The information disclosure statement filed on February 18, 2005, which is after a final rejection, has not been considered. While the fee has been paid, a statement under 37 C.F.R. § 1.97(e) is also required (see M.P.E.P. § 609).

Maintained - Claim Rejections - 35 U.S.C. § 112

3. Previous rejection of Claims 35 and 39-40 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that because the words "at least one **regulatory sequence**" (emphasis in original) are provided by the specification, that this language has adequate written description. The Examiner disagrees. No description of a *homologous* regulatory sequence is found in the specification or the art. Since the claim reads on both heterologous and homologous regulatory sequences, particularly in the absence of any recombinant requirement for the polynucleotide of Claim 35 (i.e., chimeric gene), these must be described. This rejection can be overcome by the

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inclusion of a limitation as to the non-homologous nature of the regulatory sequence with respect to the polynucleotide of Claim 29.

Applicant further argues that the instant Examiner has allowed similar language in other patents. This is not found persuasive because, as Applicant points out, each set of patent claims is examined on their own merits.

Applicant further argues citing two Court decisions without explanation about their applicability to the instant claims. The Examiner is unclear as to their applicability and cannot answer these arguments further.

Applicant further argues that regulatory sequences of *Hevea brasiliensis* are well known in the art. This may be the case; however, the instant claim requires written description for, among other things, the endogenous promoter of SEQ ID NO:1. No representative species of this genus has been described so that one of skill in the art would be able to predict what said regulatory sequence looks like.

4. Previous rejection of Claims 29-31 and 34-40 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Firstly, the Examiner notes that the GI number of the radish protein sequence is GI:1542941, not 1542940 as cited by Applicant. Similarly for *S. cerevisiae*, the number is GI:311089, not 311088 as cited.

Applicant seems to argue that the Examiner is unduly requiring examples of all claimed embodiments with the citation of Genetech, 1997; this is not the case and the record does not reflect such a requirement.

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Despite Applicant's alignment of 4 total acetyl-CoA acetyltransferases (a.k.a. acetyl-CoA thiolases, E.C. 2.3.1.9) sequences known in the art at the time of the invention, no structure/function analysis has been done with the noted sequences. The only functional assay is one of complementation, which does not identify particularly useful residues prior to random mutagenesis. As previously noted by the Examiner, what must be enabled is the ability *to make* the claimed invention, not merely *find* the claimed invention via screening procedures as referred to by Applicant citing "complementation studies demonstrate to one of ordinary skill in the art a possible manner in which to test for functional activity in sequences with the claimed identity." Moreover, conservation in the alignment presented is not necessarily indicative of enzymatic function. See for example in Ngo *et al.* wherein it is stated that no "efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone" is known (page 492). Proteins are more complex than alignments alone; structure/activity data is required to enable one of skill in the art to make the claimed invention. Thus, the Examiner maintained that using alignments alone, albeit available at the time of the invention, would not enable one of skill in the art to make the claimed invention to the full extent of the claimed scope.

Conclusion

5. Claims 29-31 and 34-40 stand rejected. Claims 32-33 stand objected to for the reasons of record and those stated herein. The finality of the previous Office action, mailed October 19, 2004, is also maintained.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

March 21, 2005